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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/395,677	09/10/1999	DOLORES M. BERGER	P-4579	6334

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/395,677	Applicant(s) BERGER ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 and 18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 12 February 2002 in Paper No. 18 in which claim 18 was amended. The amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 17 dated 20 August 2001 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 112, first paragraph are withdrawn in view of Applicant's arguments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

Currently claims 13-16 and 18-32 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 13-16, 18, 25, 26 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Essenfeld et al (U.S. Patent No. 6,207,408 B1, filed 19 August 1998).

Regarding Claim 13, Essenfeld et al disclose a method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance (Column 5, lines 28-33)having a concentration effective for denaturing proteins comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second facilitator substance (Column 5, lines 17-27) having a concentration effective for aiding the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition; contacting said at least on e cell in said sample with said composition; incubating said sample with said composition for an effective period of time and at an effective temperature; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 10, lines 8-13 Example 1, Column 16, lines 13-45 and Claim 13). The open claim language "comprising" encompasses the additional steps of Essenfeld et al.

Regarding Claim 14, Essenfeld et al disclose the method wherein the at least one alcohol or ketone is selected from the group consisting of ethanol, methanol, propanol, isopropanol and acetone (Column 5, lines 27-33 and Column 16, lines 16-23 and Claim 13).

Regarding Claim 15, Essenfeld et al disclose the method wherein said second substance is selected from the group consisting of dimethyl sulfoxide and polyethylene glycol (Column 16, lines 16-23 and Claim 13).

Regarding Claim 16, Essenfeld et al disclose the method wherein the first substance is comprised of one alcohol and one ketone (Column 16, lines 16-23 and Claim 13). The open claim language "comprised" encompasses the method of Essenfeld wherein the first substance comprises both one alcohol and one ketone.

Regarding Claim 18, Essenfeld et al disclose the method wherein the first substance is comprised of a first alcohol and a second ketone (Column 16, lines 16-23 and Claim 13).

Regarding Claim 25, Essenfeld et al disclose the method wherein the nucleic acid is DNA (Column 10, lines 8-13).

Regarding Claim 26, Essenfeld et al disclose the method wherein the nucleic acid is RNA (Column 10, lines 8-13).

Regarding Claim 31, Essenfeld et al disclose the method wherein the cell is a eukaryote i.e. biological specimen (Column 5, lines 50-56).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 19, 20, 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld et al (U.S. Patent No. 6,207,408 B1, filed 19 August 1998).

Regarding Claims 19 and 20, Essenfeld et al teach the method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance (Column 5, lines 28-33) having a concentration effective for denaturing proteins comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second facilitator substance (Column 5, lines 17-27) having a concentration effective for aiding the infusion of the first substance into said at

least one cell whose concentration is greater than 20% of the total composition; contacting said at least on e cell in said sample with said composition; incubating said sample with said composition for an effective period of time and at an effective temperature; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 10, lines 8-13 Example 1, Column 16, lines 13-45 and Claim 13) but they do not teach the concentrations of said first and second substances are in a ratio of 2.5 : 2.5 : 5 (Claim 19) or a ratio of 1:1 (Claim 20). However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the ratio of the solutions using routine experimentation to thereby derive optimal conditions for each and every cell type being stabilized for the expected benefit of maximizing experimental results.

Regarding Claim 22, Essenfeld et al teach the method wherein the first substance is comprised of a first alcohol or ketone and a second alcohol or ketone (Column 16, lines 16-23 and Claim 13) they teach the first alcohol or ketone and a second alcohol or ketone may comprise ethanol and methanol (Column 5, lines 28-37) they teach the second substance maybe dimethyl sulfoxide (Column 5, lines 17-26). Additionally, they teach functional equivalents for the components of their composition i.e. fixatives include isopropyl alcohol, ethanol and methanol (Column 5, lines 28-33) and dehydrating agents include isopropyl alcohol, methanol, ethanol and acetone (Column 5, lines 34-37) but they do not specifically teach an embodiment wherein the first alcohol or ketone is methanol, the second alcohol or ketone is ethanol and the second substance is dimethyl sulfoxide. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to alter the composition taught by Essenfeld by substituting functional equivalents also taught by Essenfeld using routine experimentation to derive optimal compositional components thereby optimize the composition for the obvious benefit of maximizing experimental results. Additionally, based on the functional equivalency taught by Essenfeld, one skilled in the art would have expected a composition comprising ethanol, methanol and dimethyl sulfoxide to

function in a similar manner within their solution. The courts have stated with regard to homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 32, Essenfeld et al teach the method wherein the cells are from any biological fluid (Column 5, lines 50-56) which clearly suggest their method is applicable to microorganisms but they do not specifically teach the cell is a microorganism. However, it was well known in the art at the time the claimed invention was made that microorganisms are cells found in biological fluids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the method of Essenfeld to microorganisms based on their teaching of any cells for the obvious benefit of stabilizing the nucleic acids of clinically important microorganisms e.g. bacteria, yeast.

6. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld et al (U.S. Patent No. 6,207,408 B1, filed 19 August 1998) in view of Evinger-Hodges et al (WO 90/02204, published 12 April 1990).

Regarding Claim 27, Essenfeld et al teach the method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance (Column 5, lines 28-33) having a concentration

effective for denaturing proteins comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second facilitator substance (Column 5, lines 17-27) having a concentration effective for aiding the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition; contacting said at least on e cell in said sample with said composition; incubating said sample with said composition for an effective period of time and at an effective temperature; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 10, lines 8-13 Example 1, Column 16, lines 13-45 and Claim 13) wherein the nucleic acid is RNA (Column 10, lines 8-13) but they do not specifically teach the RNA is ribosomal RNA. However, Evinger-Hodges et al teach a similar method for stabilizing the nucleic acids of a cell (page 13, line 29-page 14, line 3) wherein the nucleic acid is DNA, RNA or ribosomal RNA (page 6, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the RNA of Essenfeld with the ribosomal RNA taught by Evinger-Hodges et al based on the latter's teaching wherein DNA, RNA and ribosomal RNA are equally stabilized for the obvious benefits of stabilizing ribosomal RNAs for detection and/or analysis.

Regarding Claim 28, Essenfeld do not teach the effective time period is from one to four days. Evinger-Hodges et al teach the similar method wherein the effective time is 180 minutes (page 6, lines 33-34) but they do not specifically teach the effective time is about 1 to 4 days. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the effective time taught by Evinger-Hodges et al and using routine experimentation increase the time from 3 hours to 1 to 4 days (i.e. overnight or over-the-weekend) for the obvious benefit of overnight incubation i.e. the incubation can be performed in the absence of laboratory personnel.

Regarding Claim 29, Essenfeld do not teach the effective temperature is room temperature. However, Evinger-Hodges et al teach the similar method wherein the effective temperature is room temperature (page 6, line 35-page 7, line 1). It would have been obvious

to one of ordinary skill in the art at the time the claimed invention was made to modify the temperature of Essenfeld et al with the room temperature incubation taught by Evinger-Hodges to thereby eliminate the heated water-bath incubation of Essenfeld et al for the obvious benefits of simplification and convenience.

Regarding Claim 30, Essenfeld do not teach the effective temperature is from about 0° C to 40° C (Claim 30). However, Evinger-Hodges et al teach the similar method wherein the effective temperature is room temperature i.e. between 0° C and 40° C (page 6, line 35-page 7, line 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the temperature of Essenfeld et al with the room temperature incubation taught by Evinger-Hodges to thereby eliminate the heated water-bath incubation of Essenfeld et al for the obvious benefits of simplification and convenience.

7. Claims 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Essenfeld et al (U.S. Patent No. 6,207,408 B1, filed 19 August 1998) in view of Rogers (U.S. Patent No. 6,232,092 B1, filed 2 October 1998).

Regarding Claim 21, Essenfeld et al teach the method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance (Column 5, lines 28-33) having a concentration effective for denaturing proteins comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second facilitator substance (Column 5, lines 17-27) having a concentration effective for aiding the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition; contacting said at least on e cell in said sample with said composition; incubating said sample with said

composition for an effective period of time and at an effective temperature; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 10, lines 8-13 Example 1, Column 16, lines 13-45 and Claim 13) wherein the first substance comprises ethanol and methanol (Column 5, lines 28-33) and the second substance comprises dimethyl sulfoxide (Column 5, lines 17-27 and Column 16, lines 16-22) which clearly suggests a composition comprising ethanol and methanol and dimethyl sulfoxide, but they do not specifically teach an embodiment wherein the first substance is ethanol and methanol and the second substance is dimethyl sulfoxide. Rogers teaches a similar method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for denaturing proteins comprising one alcohol having a concentration of 80%; and a second facilitator substance having a concentration effective for aiding the infusion of the first substance into said at least one cell having a concentration of 20%; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 4, lines 12-15 and Column 5, line 50-Column 6, line 3) wherein the first substance is methanol and the second substance is dimethyl sulfoxide. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of the first substance taught by Essenfeld and using routine experimentation use ethanol and methanol in combination to thereby optimize the composition for maximal results for the obvious benefit of maximizing experimental results. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the dimethyl sulfoxide composition of Rogers to the suggested composition comprising enhancers, fixative and dehydrants in the method of Essenfeld to thereby provided a composition comprising ethanol, methanol and dimethyl sulfoxide based on the teaching of Rogers and based on available reagents for the obvious benefit of convenience and simplicity.

Regarding Claim 23, Essenfeld et al teach the method wherein the first substance comprises ethanol (Column 5, lines 28-33) and the second substance comprises dimethyl

sulfoxide (Column 5, lines 17-27 and Column 16, lines 16-22) which clearly suggests a composition comprising ethanol and dimethyl sulfoxide, but they do not specifically teach an embodiment wherein the first substance is ethanol and the second substance is dimethyl sulfoxide. Rogers teaches a similar method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for denaturing proteins comprising one alcohol having a concentration of 80%; and a second facilitator substance having a concentration effective for aiding the infusion of the first substance into said at least one cell having a concentration of 20%; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 4, lines 12-15 and Column 5, line 50-Column 6, line 3) wherein the first substance is ethanol and the second substance is dimethyl sulfoxide. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ethanol and dimethyl sulfoxide composition of to the suggested composition in the method of Essenfeld to thereby provided a composition comprising ethanol and dimethyl sulfoxide based on the teaching of Rogers and based on available reagents for the obvious benefit of convenience and simplicity.

Regarding Claim 24, Essenfeld et al teach the method wherein the first substance comprises methanol (Column 5, lines 28-33) and the second substance comprises dimethyl sulfoxide (Column 5, lines 17-27 and Column 16, lines 16-22) which clearly suggests a composition comprising methanol and dimethyl sulfoxide, but they do not specifically teach an embodiment wherein the first substance is methanol and the second substance is dimethyl sulfoxide. Rogers teaches a similar method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for denaturing proteins comprising one alcohol having a concentration of 80%; and a second facilitator substance having a concentration effective for aiding the infusion of the first substance into said at least one cell having a

concentration of 20%; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 4, lines 12-15 and Column 5, line 50-Column 6, line 3) wherein the first substance is methanol and the second substance is dimethyl sulfoxide (Column 5, lines 61-66). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the methanol and dimethyl sulfoxide composition of Rogers to the suggested composition in the method of Essenfeld to thereby provided a composition comprising methanol and dimethyl sulfoxide based on the teaching of Rogers and based on available reagents for the obvious benefit of convenience and simplicity.

8. Claims 13-16, 21, 25, 26, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers (U.S. Patent No. 6,232,092 B1, filed 2 October 1998).

Regarding Claim 13, Rogers teaches a method for stabilizing the nucleic acids of at least one cell in a sample comprising; adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for denaturing proteins comprising at least one alcohol or ketone whose concentration is 80% of the total composition; and a second facilitator substance having a concentration effective for aiding the infusion of the first substance into said at least one cell whose concentration is 20% of the total composition; contacting said at least on e cell in said sample with said composition; incubating said sample with said composition for an effective period of time and at an effective temperature; and obtaining at least one cell with stabilized nucleic acids in said sample (Column 4, lines 8-15 and 40-50 and Column 5, lines 61-66). Rogers do not teach the concentration of the first and second substances are less than 80% and greater than 20 % respectively. However, the compositions measured in a laboratory would differ due to a margin of error in measurement and/or evaporation and/or spillage. Therefore, the compositions prepared using the method of Rogers would most likely produce a composition comprising first and second substances are

less than 80% and greater than 20 % respectively. Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the exact concentrations of Rogers using routine experimentation to thereby derive an optimal composition for stabilizing cells because the skilled practitioner in the art would have been motivated to optimize the composition to thereby maximize stabilization. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 14, Rogers teaches the method wherein the at least one alcohol is selected from the group consisting of ethanol and methanol (Column 4, lines 40-42).

Regarding Claim 15, Rogers teaches the method wherein the second substance is dimethyl sulfoxide (Column 4, lines 40-44).

Regarding Claim 16, Rogers teaches the method wherein the first substance is comprised of one alcohol (Column 5, lines 61-66).

Regarding Claim 21, Rogers teaches the method wherein the first substance is methanol and the second substance is dimethyl sulfoxide (Column 5, lines 61-66).

Regarding Claim 25, Rogers teaches the method wherein the nucleic acid is DNA (Column 4, lines 8-15).

Regarding Claim 26, Rogers teaches the method wherein the nucleic acid is RNA (Column 4, lines 8-15).

Regarding Claim 28, Rogers teaches the effective time is about one day (Column 5, lines 61-67).

Regarding Claim 31, Rogers teaches the cell is a eukaryote (Column 4, lines 16-24).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
April 4, 2002

W. Gary Jones
Supervisory Patent Examiner
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